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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,344	01/26/2005	Dominique Swinnen	255452US0PCT	6094

22850 7590 11/16/2007

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EXAMINER	
MABRY, JOHN	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
11/16/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/501,344	SWINNEN ET AL.	
	Examiner	Art Unit	
	John Mabry, PhD	4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 9, 10, 15, 22, 23, and 27 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. This application is replete with improper multiple dependent claims. There are others. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Improper multiple dependent claims pending at the time of the first action on the merits will be objected to and, accordingly, withdrawn from examination. This application is replete with improper multiple dependent claims.

Applicant is advised that claims 19-26 are "Use" claims. Please see MPEP 2173.05(q) for information on "use" claims. "Use" claims pending at the time of the first action on the merits will be rejected and, accordingly, withdrawn from examination. For restriction purposes, the Examiner has interpreted the "use" claims as a method of treating and/or preventing.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-6, 9-17 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy=thienyl and R1 is –CH2-A or –CH2-CH2-A wherein A=phenyl. A further election of single disclosed species is required.

II. Claims 1-6, 9-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy=thienyl and R1 is –CH2-A or –CH2-CH2-A wherein A=pyridinyl. A further election of single disclosed species is required.

III. Claims 1-6, 9-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy=thienyl and R1 is –CH2-A or –CH2-CH2-A wherein A=quinoxalinyl. A further election of single disclosed species is required.

IV. Claims 1-6, 9-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy=thienyl and R1 is –CH2-A or –CH2-CH2-A wherein A=thiazolyl. A further election of single disclosed species is required.

V. Claims 1-6, 9-13, 15-17 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy=thienyl and R1 is –CH2-A or –CH2-CH2-A wherein A=thienyl. A further election of single disclosed species is required.

VI. Claims 1-6, 9-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy=thienyl and R1 is –CH2-A or –CH2-CH2-A wherein A=furanyl. A further election of single disclosed species is required.

VII. Claims 1-6, 9-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy=thienyl and R1 is –CH2-A or –CH2-CH2-A wherein A=piperidinyl. A further election of single disclosed species is required.

VIII. Claims 1-18 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy=phenyl and R1 is –CH2-A or –CH2-CH2-A wherein A=phenyl. A further election of single disclosed species is required.

IX. Claims 1-12,15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= phenyl and R1 is –CH2-A or –CH2-CH2-A wherein A=pyridinyl. A further election of single disclosed species is required.

X. Claims 1-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= phenyl and R1 is –CH2-A or –CH2-CH2-A wherein A=quinoxalinyl. A further election of single disclosed species is required.

XI. Claims 1-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= phenyl and R1 is –CH2-A or –CH2-CH2-A wherein A=thiazolyl. A further election of single disclosed species is required.

XII. Claims 1-13, 15-17 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= phenyl and R1 is –CH2-A or –CH2-CH2-A wherein A=thienyl. A further election of single disclosed species is required.

XIII. Claims 1-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= phenyl and R1 is –CH2-A or –CH2-CH2-A wherein A=furanyl. A further election of single disclosed species is required.

XIV. Claims 1-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= phenyl and R1 is –CH2-A or –CH2-CH2-A wherein A=piperidinyl. A further election of single disclosed species is required.

XV. Claims 1-2, 6-7, 9-17 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy=pyridinyl and R1 is –CH2-A or –CH2-CH2-A wherein A=phenyl. A further election of single disclosed species is required.

XVI. Claims 1-2, 6-7, 9-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= pyridinyl and R1 is –CH2-A or –CH2-CH2-A wherein A=pyridinyl. A further election of single disclosed species is required.

XVII. Claims 1-2, 6-7, 9-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= pyridinyl and R1 is –CH2-A or –CH2-CH2-A wherein A=quinoxalinyl. A further election of single disclosed species is required.

XVIII. Claims 1-2, 6-7, 9-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= pyridinyl and R1 is –CH2-A or –CH2-CH2-A wherein A=thiazolyl. A further election of single disclosed species is required.

XIX. Claims 1-2, 6-7, 9-13, 15-17 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= pyridinyl and R1 is –CH2-A or –CH2-CH2-A wherein A=thienyl. A further election of single disclosed species is required.

XX. Claims 1-2, 6-7, 9-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= pyridinyl and R1 is –CH2-A or –CH2-CH2-A wherein A=furanyl. A further election of single disclosed species is required.

XXI. Claims 1-2, 6-7, 9-12, 15-16 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy= pyridinyl and R1 is –CH2-A or –CH2-CH2-A wherein A=piperidinyl. A further election of single disclosed species is required.

XXII. Claims 1-18 and 27-29 are drawn to compounds and pharmaceutical compositions of Formula I that are not encompassed by Groups I-XXI. This group may be subject to further restriction. A further election of single disclosed species is required.

XXIII. Claims 19 and 21-22 are drawn to a method of treating and preventing metabolic disorders mediated by insulin resistance or hyperglycemia limited to the scope of one of groups I-XXII. An election of species is required if this group is chosen.

XXIV. Claims 20 and 21-22 are drawn to a method of treating and preventing diabetes type II, obesity, or appetite regulation limited to the scope of one of groups I-XXII. An election of species is required if this group is chosen.

XXV. Claims 23-26 are drawn to a method of modulating and inhibiting the activity of PTPs limited to the scope of one of groups I-XXII. An election of species is required if this group is chosen.

XXVI. Claim 30 is drawn to a method of preparing compounds of Formula I limited to the scope of one of groups I-XXII. An election of species is required if this group is chosen.

XXVII. Claim 31 is drawn to a distinct method of preparing compounds of Formula I limited to the scope of one of groups I-XXII. An election of species is required if this group is chosen.

XXVIII. Claim 32 is drawn to a distinct method of preparing compounds of Formula I limited to the scope of one of groups I-XXII. An election of species is required if this group is chosen.

XXIX. Claim 33 is drawn to a distinct method of preparing compounds of Formula I limited to the scope of one of groups I-XXII. An election of species is required if this group is chosen.

Note: For restriction purposes, the Examiner will interpret "use" claims as method of treatment/inhibition/modulation claims.

The inventions listed as Groups I-XXIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

> Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The special technical feature corresponding to Group I is a substituted methylene amide oxoacidic acid structure wherein drawn to compounds and pharmaceutical compositions of Formula I, wherein Cy=thienyl and A=phenyl. Group II contains a substituted methylene amide oxoacidic acid structure as its special technical feature, wherein Cy=thienyl and A=pyridinyl. Group III contains a substituted methylene amide

oxoacidic acid structure as its special technical feature, wherein Cy=thienyl and A=quinoxalinyl. Group IV contains a substituted methylene amide oxoacidic acid structure as its special technical feature, wherein Cy=thienyl and A=thiazolyl. Group V contains a substituted methylene amide oxoacidic acid structure as its special technical feature, whereiin Cy=thienyl and A=thienyl. Group VI contains a substituted methylene amide oxoacidic acidstructure as its special technical feature, wherein Cy=thienyl and A=furanyl. Group VII requires Cy=thienyl and A=piperidinyl as its special technical feature. Group VIII Cy=phenyl and A=phenyl as its special technical feature. Group IX requires Cy= phenyl and A=pyridinyl as its special technical feature. Group X requires Cy= phenyl and A=quinoxalinyl as its special technical feature. Group XI requires Cy= phenyl and A=thiazolyl as its special technical feature. Group XII requires Cy= phenyl and A=thienyl as its special technical feature. Group XIII requires Cy= phenyl and A=furanyl as its special technical feature. Group XIV requires Cy= phenyl and A=piperidinyl as its special technical feature. Group XV requires Cy=pyridinyl and A=phenyl as its special technical feature. Group XVI requires Cy= pyridinyl and A=pyridinyl as its special technical feature. Group XVII requires Cy= pyridinyl and A=quinoxalinyl as its special technical feature. Group XVIII requires Cy= pyridinyl and A=thiazolyl as its special technical feature. Group XIX requires Cy= pyridinyl and A=thienyl as its special technical feature. Group XX requires Cy= pyridinyl and A=furanyl as its special technical feature. Group XXI requires Cy= pyridinyl and A=piperidinyl as its special technical feature. Group XXII require all other structures that

are not encompassed by Groups I-XXI as its special technical feature. The ring systems are not considered equivalent.

The technical feature corresponding to the methods claims of Groups XXIII, XXIV and XXV are: method of treating and preventing metabolic disorders mediated by insulin resistance or hyperglycemia, a method of treating and preventing diabetes type II, obesity, or appetite regulation, and a method of modulating and inhibiting the activity of PTPs, respectively - found in the individual compound and composition groups above. There is a significant difference in the between compounds/composition and methods of treating a disease/condition and method of inhibition. These treatments of diseases/conditions and compounds/compositions are not considered equivalent.

The technical feature corresponding to the methods claims of Groups XXVI, XXXVII, XXVIII and XXIX are: distinct methods of preparing compounds of Formula I - found in the individual compound and composition groups above. There is a significant difference in the between distinct synthetic processes of preparation of these groups. These treatments of diseases/conditions, compounds/compositions and processes of preparation are not considered equivalent.

The special technical feature of this invention is the common core found in Formula I. This special technical feature, found in WO 02/18321 A2 as described by Lui

et al (Example 5, (benzyl(2,3-dichloro-4-(1-naphthyl)benzyl)amino)-(oxo)acetic acid, page 29) – reference already of record.

Therefore the above claims, are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a common core structure and the technical features present fail to define a contribution over the prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to only one invention.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Rejoinder Advisory

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JM

RITA DESAI
PRIMARY EXAMINER
11/07/07